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Exactech® Novation® InteGrip™ Acetabular Augments
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: Vladislava Zaitseva
Regulatory Affairs Specialist

Date: January 4, 2012

Trade or Proprietary or Model Name(s):
Exactech® Novation® InteGrip™ Acetabular Augments

Common Name:
Acetabular Augment

Classification Name:
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358, Device Class: II, Product Code: LPH)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K101761	Exactech Novation InteGrip Acetabular Augments	Exactech, Inc

Indications for Use:
The Exactech Novation InteGrip Acetabular Augments are indicated for use in skeletally mature individuals undergoing primary or revision surgery for hip replacement and whose orthopedic surgeon desires a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

The Exactech Novation InteGrip Acetabular Augment is affixed to the mating acetabular shell using PMMA bone cement. Therefore, acetabular shells with HA coating must not be used with InteGrip Acetabular Augments. The assembled construct is intended for press-fit fixation.

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Exactech® Novation® InteGrip™ Acetabular Augments
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Device Description:
The proposed Exactech Novation InteGrip Acetabular Augments are a modification of the Exactech InteGrip Acetabular Augments cleared through premarket notification #K101761.

The predicate and proposed devices have the same intended use and the same basic fundamental scientific technology.

The modified devices share the following similarities with predicate devices:

- Indications for Use
- Design Features (e.g. screw holes, height configurations)
- Material (titanium alloy)
- Shelf Life (5 years)
- Packaging and sterilization materials and processes (gamma radiation sterilization to a sterility assurance level of 10^{-6})

The proposed devices include the following design change:

- Expand the current scope of augments to include sizes that are compatible with the Novation Crown Cup acetabular shell sizes 60-68mm (both plasma spray and InteGrip).

Substantial Equivalence Conclusion:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed device to the predicate Exactech Novation InteGrip Acetabular Augments:

- An engineering evaluation to determine that the geometric features of the proposed devices correspond to the compatible acetabular shells and are dimensionally and functionally similar to the predicate devices.

In addition to the design similarities, the results of engineering analyses demonstrate the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN - 4 2012

Exactech® Inc.
% Ms. Vladislava Zaitseva
2320 N.W. 66th Court
Gainesville, FL 32653

Re: K113609
Trade/Device Name: Exactech® Novation® InteGrip™ Acetabular Augments
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: December 5th, 2011
Received: December 6th, 2011

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® InteGrip™ Acetabular Augments
Special 510(k) – Indications for Use

510(k) Number: K113609

Device Name: Exactech® InteGrip™ Acetabular Augments

INDICATIONS

The Exactech Novation InteGrip Acetabular Augments are indicated for use in skeletally mature individuals undergoing primary or revision surgery for hip replacement and whose orthopedic surgeon desires a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

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Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113609